

# Notice of Allowability

## Application No.

09/818,939

## Examiner

Sheridan L. Swope

## Applicant(s)

KARIMOVA ET AL.

## Art Unit

1652

### -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amdts of September 16, 2004 and December 13, 2004.
2. ☒ The allowed claim(s) is/are 97,98,100-105,119-140 and 143-146.
3. ☒ The drawings filed on March 28, 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|   | 9. <input type="checkbox"/> Other _____.   |

Art Unit: 1652

**DETAILED ACTION**

Applicant's response, on November 10, 2004 to the Final Rejection of this case mailed September 16, 2004, as well as their Supplemental Amendment of December 13, 2004, are acknowledged. It is acknowledged that applicants have cancelled Claims 96, 99, 106-118, 141, and 142 and amended Claims 100, 101, 124, 129, 134, and 140. Claims 97, 98, 100-105, 119-140, and 143-146 are pending. Claims 119-140, and 143-146 were withdrawn from further consideration in the action of September 16, 2004 pursuant to 37 CFR 1.142(b). Claims 97, 98, and 100-105 are hereby reconsidered.

***Claim Rejections - 35 USC § 101-Double Patenting***

Claims 96-107 were provisionally rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 2-5 and 8 of of US Application SN10/240,102. In response to said rejection, Applicants request that the Office withdraw the rejection and allow Claims 97, 98, 100-105, 119-140, and 143-146 to issue in the instant application. Applicants submit that any issue relating to obviousness-type double patenting may then be addressed, if appropriate, in the 10/240,102 application. Based on this statement by Applicants, provisional rejection of Claims 96-107 under 35 USC § 101 as being unpatentable over Claims 2-5 and 8 of US Application SN10/240,102 is withdrawn.

***Examiner's Amendment***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Art Unit: 1652

In Claims 143-146, lines 3-4, delete –the color marker is Green Fluorescent Protein (GFP);– .

Authorization for this examiner's amendment was given in a telephone interview with Debra Katz on December 13, 2004.

*Allowable Subject Matter*

Claims 119-140 and 143-146 are rejoined.

Claims 97, 98, 100-105, 119-140, and 143-146 are allowed.

The following is an examiner's statement of reasons for allowance:

All elected Claims, 97, 98, 100-105, 119-140, and 143-146, are limited to a signal amplification system, comprising a first chimeric protein comprising a first fragment of Bordetella adenylate cyclase fused to a molecule of interest and a second chimeric protein comprising a second fragment of the cyclase fused to a target ligand wherein activity of the cyclase is restored when the molecule of interest binds to the target ligand as well as the use of said amplification system to detect a molecule of interest. The utility of said amplification system in identifying a molecule of interest is credible based on the ability of the system to detect binding of the urease accessory protein UreH (HP0067) to a known target (Example 6). Furthermore, the use of the unique E. coli strains BTH101 and DHM1 renders the signal amplification system non-obvious over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Art Unit: 1652

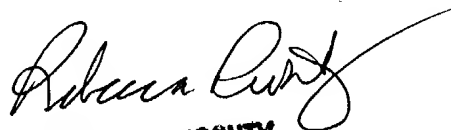
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943.

The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan Lee Swope, Ph.D.

  
REBECCA E. PROUTY  
PRIMARY EXAMINER  
GROUP 1600  
1600